

DOCKET NO.: BMS-0650
Application No.: 09/281,474
Office Action Dated: January 13, 2003

PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116

REMARKS

Claims 1-10, 12-35 and 48-50 are pending after the above amendment. Claims 1, 2, 4-6, 12-35, 48, and 49 have been amended. Claim 11 has been canceled without prejudice.

Double Patenting

The claims stand rejected under the doctrine of obviousness-type double patenting over Application Serial Nos. 09/465,300 (now U.S. Patent 6,511,648), 09/466,582, 09/599,364 (now U.S. Patent 6,511,649), 09/281,209 (now U.S. Patent 6,524,553), and 09/948,807. Applicants respectfully traverse the rejection, and appreciate the Examiner's indication that the rejection need not be rebutted until the withdrawal of all other rejections.

Obviousness

Claims 1, 2, 11¹-15, 17, 19-23, 25, 27, 28, 31-35, 48, and 49 have been rejected under 35 USC §103 over U.S. Patent No. 5,780,426 ("Palladino"). Applicants respectfully disagree with the rejection, and submit that the claims, as presented to the Patent Office in the Amendment dated October 18, 2002, define over this reference. In this regard, Applicants note that the Office action states that "a skilled practitioner in the art would recognize [sic] that as the composition of Palladino may be a peptide-chelator complex." As discussed in MPEP 2141.02, for a rejection under §103 to be proper, the prior art reference must render obvious the subject matter of the claimed invention *as a whole*. Moreover, MPEP 2141.02 clearly states that "[d]istilling an invention down to the 'gist' or 'thrust' of an invention disregards the requirement of analyzing the subject matter 'as a whole.'"

¹ Applicants note the Office action rejected claims "1, 2, 1-15" etc., but proceed under the assumption that the Office action intended to reject claims 1, 2, 11-15 etc.

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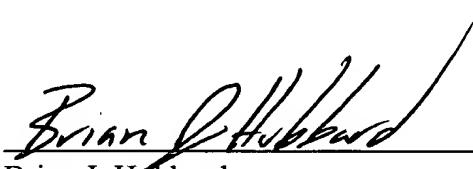
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Palladino teaches a broad group of penetration *enhancers for peptide absorption* "through ocular, buccal, transdermal, rectal, nasal inhalation or oral inhalation." These enhancers include surfactants, nonsurfactants, bile salts, fatty acids, and "chelators." The latter term is mentioned just once in Palladino's entire disclosure. Palladino fails to disclose a procedure or method for attaching the chelator to the peptide, in fact, Palladino does not teach that the chelators may be attached to the peptide at all. Moreover, the "chelators" are limited to "EDTA, citric acid, N-acyl derivatives of collagen, enamines (N-Amino N-acyl derivatives of β -diketones)" (Palladino, col. 16, line 66 - col. 17, line 1). Thus, it is respectfully submitted that Palladino simply does not teach or suggest a chelator within the spirit of the Applicants' specification, and fails to show that the claimed invention *as a whole* would have been obvious.

Nevertheless, to advance prosecution, Applicants have amended Claim 1 to further define the linking group, and have canceled Claim 11 without prejudice.

Entry of the foregoing amendment and an early Notice of Allowance are respectfully requested. If the Examiner has any questions, the Examiner is invited to call the undersigned representative at (215) 568-3100.

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